

# EXHIBIT 7

**AMERICAN ARBITRATION ASSOCIATION  
NEW YORK, NEW YORK**

ACORDA THERAPEUTICS, INC.,

*Claimant,*

v.

ALKERMES PLC,

*Respondent.*

AAA Arbitration No.  
01-20-0010-8421

Arbitrators:

Hon. Jose L. Linares

Hon. Arthur Gajarsa

Hon. Robert S. Smith

**-- CONFIDENTIAL --**

**ACORDA THERAPEUTICS, INC.'S POST-TRIAL BRIEF**

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## INTRODUCTION

Before being acquired by Alkermes in 2011, Elan recognized that it would *not* be entitled to continue charging Acorda royalties after expiration of the '938 Patent based solely on alleged know-how. Elan's in-house patent attorney, Richie Paul, made that crystal clear in his 2009 internal memo. C160. But after the merger, Alkermes rejected Acorda's *Brulotte* letter and other pleas to stop paying onerous post-patent expiration royalties by asserting know-how as the sole basis to continue collecting unlawful royalties. Incredibly, Alkermes's CEO testified that he never spoke with Paul—Alkermes's current global head of IP—about this reversal. C160. Yet, Mr. Paul authored the response to Acorda's final pre-arbitration letter that was addressed to Alkermes's CEO. C119. The CEO did admit that Alkermes refused to refund royalties in part because it had already booked Acorda's payments as income (C120)—not because it was entitled to do so.

As a result, Alkermes has done exactly what the Supreme Court outlawed in *Brulotte* and *Kimble*. *First*, it has made a bald attempt to exact the same terms and conditions (the 10% license royalty) for the period after the '938 Patent expired as it did for the monopoly period. *Second*, it has extended the “monopoly influence” of its expired patent to coerce Acorda into paying a grossly over-market supply price after patent expiry and generic entry—resulting in an outrageous *811% profit margin* on supply in a generic market! Even if Alkermes did not manufacture the product,

Acorda would still be contractually obligated to pay Alkermes a “Compensating Payment” equal to the full 8% supply royalty (less de minimis manufacturing costs).

Leveraging its '938 Patent—a blocking patent that was the gateway to 4-AP clinical research—Alkermes rejected the request by Acorda’s CEO, Dr. Ron Cohen, to license the patent without tying the license to supply. Had Alkermes refrained from such coercion, Acorda would have contracted with one of the other manufacturers then available to make Ampyra at a significantly reduced supply price and Acorda’s business would not have been placed in “dire straits” when Alkermes violated *Brulotte*. Acorda would have been paying market price for third-party supply and could have simply stopped paying the 10% license royalty to Alkermes upon patent expiry—without endangering its supply—and arbitrated the dispute as to future 10% payments only. This would have saved Acorda nearly \$81 million in combined unlawful license and supply royalty payments to Alkermes post-patent expiry (C25, C47)—which significantly damaged Acorda’s business and market value. Also, Acorda would have been better-positioned to compete with generics who have never been burdened by these unlawful royalties. Beyond the royalty payments, Alkermes further allocated all of the risk and cost to Acorda by requiring Acorda—which paid for its own clinical research—to pay for Alkermes’s employees’ time spent on development work, plus a *45% mark-up*.

Alkermes proffers several alternative, overlapping excuses for continuing to collect the same royalty rates in perpetuity—some of which it formulated late in the arbitration while preparing for trial. But none are supported by the evidence, nor are they recognized by applicable law, as shown below. The Agreements at issue are thus unlawful *per se* and unenforceable. Acorda is entitled to the relief it seeks.

## **CONCLUSIONS OF LAW BASED ON THE TRIAL EVIDENCE**

### **I. THE TRIAL EVIDENCE PROVED A *BRULOTTE* VIOLATION**

The License Agreement is unlawful *per se* and violates *Brulotte* because it requires payment of the Elan royalty for the '938 Patent beyond the patent's expiration. Unable to dispute that Acorda paid royalties after the '938 Patent expired—and unwilling to admit it charged the *same royalty rate* before *and after expiration*—Alkermes asks the Panel to adopt a tortured reading of *Brulotte* and its progeny and perform mental gymnastics to recharacterize the contract, royalty rate, and inevitable conclusion.<sup>1</sup> These are not new “tricks”—other licensors presented them only to be rejected in *Brulotte*, *Kimble* and subsequent cases.

#### **A. Royalty-Based Agreements That Extend A Patent Monopoly Beyond Its Expiration Are Unlawful *Per Se*.<sup>2</sup>**

Any patent license that “exact[s] the same terms and conditions for the period after the patents have expired as [it does] for the monopoly period” violates the

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<sup>1</sup> Tr. 90:19-20 (Chm Linares: “So the stepdown is from 10 percent to 10 percent?”).

<sup>2</sup> *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964).

public policy of the federal patent law system, and is unenforceable.<sup>3</sup> In fact, “all patent-related benefits must end when the patent term expires.”<sup>4</sup> Under New York law, courts strictly apply this *per se* illegality:

A patent holder cannot use the grant of a license as means of extending the lawful term of the patent monopoly. A “patentee’s use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*.” [quoting *Brulotte*] The use of such an arrangement constitutes patent misuse *even in the absence of evidence demonstrating that the patent holder used the leverage of the patent coercively to impose an extended term on the licensee*.<sup>5</sup>

**B. Under The 2003 Agreements, Alkermes Unlawfully Demanded And Collected Royalties Beyond Expiration Of The ’938 Patent.**

Acorda proved that Alkermes used the ’938 Patent to exact the onerous terms and conditions that are found in the underlying Agreements. C53-54; C202-204. “The use of the [’938 Patent] to obtain an agreement for payment of compensation beyond the expiration of the patent renders the Agreements unlawful *per se*.”<sup>6</sup>

Acorda pays a 10% royalty on sales of Ampyra in undifferentiated consideration of Elan Patents and Elan Know-How. C21, C24, C129-135, C210. Because there is no separate provision for Elan Know-How triggered by the expiration of the Elan Patents, the same royalty has been charged before and after

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<sup>3</sup> *Id.* at 32; *see infra*, Section II.A.3.

<sup>4</sup> *Kimble v. Marvel Ent. LLC*, 576 U.S. 446, 448 (2015).

<sup>5</sup> *Leesona Corp. v. Varta Batteries, Inc.*, 522 F. Supp. 1304, 1342 (S.D.N.Y. 1981) (emphasis added) (citing authority).

<sup>6</sup> *Sanford Redmond, Inc. v. Mid-America Dairymen, Inc.*, No. 85 Civ. 4574(RJW), 1992 U.S. Dist. LEXIS 2376, \*17-18 (S.D.N.Y. 1992).

patent expiration. C24; C130-34. It is undisputed that Alkermes demanded the same royalty rate before and after the '938 Patent's expiration (increased to 11% because the Rush license expired). When Acorda asked to modify the royalty structure in light of the '938 Patent's expiration, Alkermes saw no reason to change its demand. C25, C106-109. As Alkermes's chief negotiator admitted, notwithstanding patent expiration, the "royalty continues to be paid for the length of the agreement." C131. And Acorda cannot terminate without forfeiting the ability to sell Ampyra for at least one year. J-001 (Art. 2.2; 12.5.5.2); J-002 (Cl. 12.2.2).

## **II. ALKERMES FAILED TO SHOW A *BRULOTTE* RULE EXCEPTION**

In *Kimble*, the Supreme Court explained how parties could draft a patent licensing agreement that provides flexibility as to the structure and timing of royalty payments on patent and non-patent rights without violating *Brulotte*. It identified scenarios that could be exceptions to the *Brulotte* rule. Alkermes argues three are relevant: a purported step-down provision, a joint venture relationship, and a reallocation of royalty payments. But none apply.

### **A. There Is No Step-Down Provision.**

When a licensing agreement covers both patent and non-patent rights, royalties for the non-patent rights must be clearly delineated from the royalties due for patent rights.<sup>7</sup> Without a separate provision setting forth the reduced royalty rate

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<sup>7</sup> *Kimble v. Marvel Enterprises, Inc.*, 576 U.S. at 454.

for non-patent rights, the Supreme Court presciently previewed the exact harm that has come to fruition here: a patent owner will leverage its lawful ability “to exact royalties as high as [it] can negotiate . . . to project those royalty payments beyond the life of the patent” and assert “monopoly power in the post-expiration period when . . . the patent has entered the public domain.”<sup>8</sup> Thus, the need for a step-down provision. Such a provision demonstrates the parties’ mutual knowledge of and agreement to the composition of intellectual property comprising the patent and non-patent rights as well as the *independent* value of each.<sup>9</sup> The 1999 Elan/Janssen Agreement, which also dealt with a small molecule drug, includes an example of a lawful step-down provision. C112-13. It distinguishes clearly between patent and know-how royalties and sets forth a reduced royalty for know-how following patent expiration. Ex. C-880 at -010-011. Had Elan wanted to include a lawful step-down provision in the 2003 Agreements with Acorda, it certainly knew how to write one. Alkermes had an opportunity to negotiate a step-down after the ’938 Patent expired. C111-121. Alkermes refused, instead taking advantage of Acorda’s “dire straits” (C149) to draw out these proceedings and collect unlawful royalties.

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<sup>8</sup> *Brulotte*, 379 U.S. at 180.

<sup>9</sup> *Pitney Bowes, Inc. v. Mestere*, 701 F.2d 1365, 1372-73 n. 12 (11th Cir. 1983); *Indus. Promotion Co. v. Versa Prod., Inc.*, 467 N.W.2d 168, 172 (D. Wis. 1991) (royalties paid under agreement with patent and non-patent rights post-expiration were unlawful “because there [was] no distinction and no reduction or any change in patent royalties as distinguished from compensation for know-how”).

Further, the notion of a step-down provision in the 2003 Agreements is a complete farce. Elan—who negotiated the Agreements—communicated internally in 2009 its understanding that after expiry, the '938 Patent would “no longer trigger a royalty to Elan under the [License] Agreement.” C160. As Mr. Paul stated emphatically in his memo, such result could be avoided only if inventorship of the Acorda Patent was changed (which it was not). *Id.* The Elan memo thus acknowledged that Elan “know-how” could not support a continued 10% royalty after expiration of the '938 Patent. *Id.* No Alkermes witness testified to any internal disagreement about the memo, and Mr. Paul testified he was aware of none. C160.

Recognizing that no provision in the License Agreement contains a lawful step-down provision (C136-142), Alkermes propounds an after-the-fact—and wrong—argument: combining License Royalties (Article 5.2) and Milestone Payments (Article 5.3) with the Elan Royalty to create a “patent royalty” higher than the “know-how royalty”. Tr. 85:23-88:6 (Alkermes Opening). But this contradicts the plain language of the License Agreement. The Elan Royalty is defined in Article 5.6.1 and *it does not include* License Royalties or Milestone Payments. Further, neither Article 5.2 nor Article 5.3 reference the Elan Royalty. C152-153.

Unsurprisingly, there is no clear step-down for Elan Know-How in the License Agreement since Alkermes never identified this know-how with any specificity, claiming it was “secret.” C20. Had the License Agreement included a

provision that after expiration of the Elan Patent Rights a royalty would be owed on Elan Know-How, Alkermes would have had to explain what the know-how was and substantiate its value. That never happened at trial or otherwise. C20, C59-C60.

1. Alkermes’s Only Purported Know-How Valuation Evidence—  
An Unreliable Opinion—Should Be Disregarded.

Alkermes’s only attempt at placing a value on its supposed know-how stems from the fatally flawed and wholly unreliable testimony of its expert, Dr. Addanki, who opines that a royalty rate of 10% or greater is reasonable even after expiration of the ’938 Patent. He claims that Ampyra’s post-generic-entry market share was “unusually high,” which he claims can only be attributed to Alkermes’s alleged know-how. But in reaching that conclusion, Dr. Addanki compares the industry average for brand market share one year after generic entry in *2013-2014* (7%) to Ampyra’s market share one year after generic entry in 2020 (19.5%). C79, C82-84. Dr. Addanki admitted that had he instead used data from when Ampyra went generic *in 2018*, his calculations would have changed dramatically (C79-C80, C81-85), undermining his ultimate conclusion of a “reasonable” royalty. Indeed, had he used the appropriate benchmark from the updated 2021 Grabowski Article (C-1012), he would have compared the 18% (instead of 7%) industry average in 2017-2019 to Ampyra’s 19.5% market share and reached the *correct* conclusion that Ampyra performed only marginally better (1.5%) than the industry average. C76-77, C81, C94, C96-C100; C201. Any argument that Ampyra’s 2019 market share is relevant

for this comparison is belied by Dr. Addanki's own testimony and use of the 2020 19.5% market share for that comparison. C76. Moreover, Acorda's economics expert, Mr. Malackowski explained why the updated 2021 Grabowski article and 2017-2018 data is an appropriate benchmark: removing Ampyra from would not have changed the industry average. C76, C87-88; C95.

As Mr. Malackowski also explained, Ampyra's marginally above-average performance is attributable to Acorda's extensive patient support services and other measures to build brand loyalty (C72, C89-92), not due to purported Know-How. C87 (Acorda concluded there was "no 'there' there" as to Alkermes Know-How.). Unsurprisingly, neither Alkermes nor its expert offer any evidence of a nexus between Know-How and performance. C86, C88. Nor could they. Alkermes's argument is unsupported conjecture refuted by the FDA's finding of bioequivalence for each of the nine generics and should be disregarded. C172-173, C175.

## 2. Alkermes's "Last Stand" Also Fails Because Elan Know-How Simply Does Not Exist.

Valuation aside, Alkermes's argument that there is Elan Know-How is divorced from the definition in the License Agreement. It fails to account for information that is outside of Elan's oral release technology (C155), for what is generally known and routine in drug manufacture (C163-166, C179), and for preexisting know-how that belonged to RUSH (the first manufacturer of a 4-AP investigational product) or the joint venture MS R&D (C180-185). None of what

Alkermes touts can be considered Elan Know-How. C176-C178, C186-C198. It is no wonder that, when pressed at trial, Alkermes was unable to articulate the “valuable” know how that it has long touted to this Panel.

Instead, Alkermes identified three general categories of alleged Elan Know-How: Impurity, Tableting, and Moisture Control. Recognizing that these are all standard and routine oral dosage form characteristics to be tested and modified, Elan argues that it is the tests for these categorical characteristics and/or specific results. Elan’s argument is not credible. Elan’s work was all routine and/or used standard equipment or tests and well-known specifications FDA required. C158, C171, C188.

The specific formulation of Ampyra is not Elan Know-How. Ampyra’s formulation has been public since at least 2011. C193. The Ampyra formulation uses an oral controlled release platform technology referred to as MXDAS (C164), which Elan described as “formulated using conventional equipment and processing methods.” C171. All of the ingredients in MXDAS Ampyra were disclosed publicly in patents and on the Ampyra label. C196. And, even assuming there was Elan Know-How when Ampyra was first formulated with MXDAS technology, in the intervening 27 years of patent disclosures, generic entrants, peer-reviewed research, regulatory disclosures, and scientific advancement, any Elan Know-How has become public. C166, C171, C199-200. In addition, Alkermes disclosed its Know-How in its development report within the Hatch-Waxman Litigation.

Alkermes struggles to point to Elan Know-How within Elan's "oral controlled release technology." So instead, it simply read this requirement out of the Elan Know-How definition. Elan's expert, Dr. Chambliss admitted this, noting he did not consider this part of the definition at all. C183. This mistake is fatal to Dr. Chambliss's credibility and expert opinions. In contrast, Acorda's expert Dr. Appel confirmed that "Elan's oral controlled release technology," *i.e.*, MXDAS, was known or generally available to the public. C183. MXDAS uses excipients that were both commercially available and exceedingly common by 2018. C195.

Elan formulator Meyers admitted it took only a matter of weeks in 1995 to formulate Ampyra with MXDAS. C164-166. The formulation uses polysaccharide and hydrophilic matrix polymers to control drug release, specifically Avicel and Methocel, which are two of the most common, commercially-available polymers. C167-170. Elan's own documents indicate the MXDAS platform uses only conventional equipment and methods. C171. The active ingredient in Ampyra (4-AP) was also a known compound with a long clinical history at the time Elan began its work. C152. It was well-characterized by 2018. C173. And, its manufacture and impurity profile cannot be Elan Know-How per the definition: Elan/Alkermes does not manufacture the drug substance; it *purchases* 4-AP from other companies. C178.

Despite this fact, Alkermes focused on the impurity profile of 4-AP and the methods used to test Ampyra as Elan Know-How. Yet, to date, over twenty 4-AP

impurities have been identified and catalogued, which *include* all impurities mentioned in the NDA. C176. Moreover, it is undisputed that quantifying and identifying impurities using chromatography is FDA-mandated and routine. C177. The stability testing and impurity identification process used by Elan was also the process the FDA instructs companies to use for hydrophilic matrix tablets. U47-54, C167-68.

Alkermes appears to argue that because the CMC is confidential, its contents are Elan Know-How. Yet, the Australian Department of Health, the European Medicines Agency, the FDA, multiple peer reviewed articles, patents, and Hatch-Waxman litigation documents publicly described Ampyra's impurities, formulation, manufacture, and development even before expiry of the '938 Patent. C182-185. The FDA also issues guidelines specifying exactly what must be included in the CMC section of an NDA or an ANDA for a drug product to get approval. C157. Acorda paid Elan/Alkermes to use established methods to generate the CMC per the FDA's specific guidelines. C158. Each of the nine approved generics submitted its own CMC meeting the same FDA specifications, C173, and showed it obtained the correct release profile, stability, shelf-life, etc. as Ampyra. C172-177.

Importantly, Acorda *paid for* and *owns* the NDA and CMC—putting the lie to Alkermes's reliance on the CMC for the existence and value of Elan Know-How. Indeed, the NDA is Dr. Chambliss's entire basis for the continued value of Elan

Know-How. C167. But any “knowledge, information, trade secrets, data and expertise . . . owned or possessed by Acorda” constitutes *Acorda* Know-How not *Elan* Know-How. C156. Acorda paid Alkermes millions of dollars—at a 45% markup—to generate and deliver the CMC section for Acorda. C30-32; C62-64. Alkermes’s scientists, including Padraig Glynn, knew they were working on behalf of Acorda while generating the CMC. C68. Acorda is incredulous that Alkermes is now asking for a royalty based on Acorda’s CMC. The CMC’s contents are not the only Acorda-owned data and information Alkermes claims for itself. Dr. Chambliss admits he did not consider Rush Know-How and former JV MS R&D Know-How, which Acorda, *not Elan*, purchased or licensed. C182-84; C180-181.

In sum, despite having two years to identify *Elan* Know-How specifically in this arbitration, Alkermes chose to argue that everything under the sun is *Elan* Know-How. In overreaching it identified nothing distinguishable from the work paid for or even conducted by *others* (Acorda, Rush, MS R&D, Regis, excipient suppliers, the list goes on)—much less establish royalty-bearing Know-How that is *within Elan’s oral controlled release technology* and is *not* generally available to the public.

**B. The License Agreement Was A Royalty Bearing Agreement—And States That It Was *Not* A Joint Venture.**

Far from being a joint venture (JV) partner, Alkermes leveraged its ’938 Patent in violation of *Brulotte* to ensure that Alkermes profited after patent expiry and generic entry—despite the enterprise-threatening risk and damage to Acorda.

By torturing the concept of “collaboration,” Alkermes attempted to prove the JV exception. But Alkermes failed to carry its burden.<sup>10</sup>

*First and foremost*, the plain language of the License Agreement in Article 12.7 expressly states the parties’ intent *not* to form a partnership, JV, or similar business relationship through the 2003 agreements. C35, C144. On cross-examination, Alkermes’s CEO, Mr. Pops, conceded that he had omitted any reference to this critical, dispositive fact from his direct testimony. C36. The 2003 Agreements expressly dissolved the JV entity, MS R&D, created by the 1998 License and Supply Agreement, to address pending charges by the Securities and Exchange Commission (“SEC”)<sup>11</sup>, and Acorda *alone* assumed all of that entity’s rights, title, interests, and obligations. C18, C33-34, C56-57, R22. *Second*, the JV exception excludes *royalty-based* agreements like the 2003 Agreements. C143.<sup>12</sup>

*Third*, Alkermes did not and could not establish the required partnership/JV elements: (1) sharing of profits and losses; (2) joint control and management over the business or venture; (3) contribution by each party of something of value such

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<sup>10</sup> *Cosy Goose Hellas v. Cosy Goose USA, Ltd.*, 581 F. Supp. 2d 606, 620 (S.D.N.Y. 2008) (“The party seeking to evince the existence of a joint venture must establish [the] elements.”).

<sup>11</sup> Acorda requests that the Panel take judicial notice of the SEC investigation. Fed. R. Evid. 201(b); *Chevron Corp. v. Donziger*, 974 F. Supp. 2d, 362, 387 n. 14 (S.D.N.Y. 2014); Acorda’s Prehearing Brief at 8.

<sup>12</sup> *Kimble*, 576 U.S. at 454 (“*Brulotte* poses no bar to business arrangements *other than royalties*...that enable parties to share the risks and rewards of commercializing an invention.”) (emphasis added).

as property, skill, financial resources, knowledge, or effort; (4) expressed intent to be partners or joint venturers (which is a fiduciary relationship), and (5) entry into an agreement to create “an enterprise for profit.”<sup>13</sup> The first element is not met where, as in the 2003 Agreements, there is “no agreement as to the manner in which the parties were to share in the profits and the losses, the agreement did not create a joint venture or a partnership.” *Id.* at 171-172 (cleaned up). C145. Instead, there is explicit language demonstrating that *Acorda paid* for everything contributed by Alkermes. C62-C67. Alkermes admitted at trial that it charged Acorda a full-time employee rate (FTE) with 45% mark-up for all of its development work, amounting to millions of dollars by the time the FDA approved Ampyra. C31. Alex Nesbitt, Alkermes’s chief negotiator, testified that Alkermes simply wanted to maintain its “economics”: 18% of net sales under the 1998 Agreement. C47, C60-C61, C133. And when Ampyra faced generic entry, it was Acorda, *not* its supposed “JV partner” Alkermes, who was in “dire straits financially” due to the resulting 85-90% decline in Ampyra’s sales (C136-C137)—a loss compounded by Alkermes’s ongoing demand for an 18% royalty (including Alkermes’s *811% profit margin* on supply).

Any argument by Alkermes to the contrary, such as that its contribution of a CMC Section—paid for and owned by Acorda—constitutes a sharing of profits and

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<sup>13</sup> *Kidz Cloz, Inc. v. Officially For Kidz, Inc.*, 320 F. Supp. 2d 164, 171 (S.D.N.Y. 2004).

losses resulting from a fiduciary relationship, is not credible.<sup>14</sup> Alkermes cannot argue it bore any financial risk under the 2003 Agreements for the development and commercialization of Ampyra. Alkermes provided no financing for the clinical trials, charged Acorda for all clinical supply, and invoiced Acorda at FTE + 45% for its development work. Acorda bore these financial obligations alone.

While the Panel need not consider the remaining elements, Alkermes failed to satisfy its burden as to those elements as well. For example, Alkermes did not establish joint control and management—after the dissolution of MS R&D there was no entity or enterprise for the parties to jointly manage. As Mr. Pops admitted, the License Agreement does not allocate to the joint Committee any decision-making authority, a means of hiring employees shared by Alkermes and Acorda, a management structure with a hierarchy of Alkermes/Acorda team members, or voting procedures. C38-42. As to contributions, to the extent Alkermes contributed anything of value under the License Agreement, Acorda had to *purchase* those contributions from Alkermes. C66-71. The last element is not satisfied because the JV entity MS R&D was explicitly dissolved in the 2003 agreements. C18.

The parties' relationship was one of leveraged business positions and those scales always tipped in favor of the larger, multi-product, greater-resourced

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<sup>14</sup> See *Kidz*, 320 F. Supp. at 171-172; *Cosy*, 581 F. Supp. 2d at 621-23; *Kimble*, 576 U.S. at 454.

Alkermes, and its '938 “blocking” patent. C5-10, C15-16, C19-22, C26-29, C53-54, C61-62, C65, C128-130, C146-151. Alkermes leveraged its position *not* to share in the risks and rewards of developing Ampyra, but rather to ensure it profited *regardless* of the risk and harm to Acorda. C10, C54.

**C. Reallocating Or Recharacterizing The Other Monetary Provisions In The License Agreement Does Not Avoid *Brulotte*.**

Alkermes contends that Acorda’s up-front and milestone payments were used to “buy down” the patent royalty *during the time the '938 Patent was valid*, making the pre-expiry royalty for the '938 Patent larger than the post-expiry royalty. But there is absolutely no support in the License Agreement or the trial record for this slight-of-hand. Alkermes’s own witness, Mr. Nesbitt, belies this theory. According to him, the royalty rates set forth in the 2003 Agreements (10% license and 8% supply), were to be the same royalty “that Acorda was paying 18 percent overall as it was in 1998.” C59, C133. The notion that the 10% rate in the 2003 Agreement was a reduced, “buy-down” amount is simply untrue. The Supreme Court rejected this argument in both *Brulotte* and *Kimble*, where the licensee made up-front lump sum payments in addition to the royalty.<sup>15</sup>

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<sup>15</sup> See *Kimble*, 727 F.3d at 858 (up-front payment of \$516,214.62); *Brulotte*, 379 U.S. at 29 (“Respondent . . . sold a machine to each of the petitioners for a flat sum and issued a license for its use.”).

**III. ALKERMES WAS UNJUSTLY ENRICHED UNDER THE SUPPLY AGREEMENT BASED ON THE *BRULOTTE* VIOLATION.**

The 8% percent “Supply Price” Alkermes continues to extract from Acorda is a grossly over-market supply royalty based on Alkermes’s *Brulotte* violation, paid pursuant to an unenforceable provision. (The 4.25% royalty rate applies only if Alkermes is not manufacturing the product, which it is. C131. It is not a step-down.)

**A. The Supply Agreement Is An Extension Of The *Brulotte*-Violative License Agreement.**

As the Panel has held, the Supply Agreement is an extension of the License Agreement. C200. Dr. Cohen testified that in 1995, he asked Elan to negotiate a license for the ’938 Patent only, without entering into any manufacturing relationship with Elan, but Elan refused. C10. But Acorda needed to license the rights to Elan’s ’938 Patent which covered all controlled-release formulations of 4-AP and therefore blocked all other research and patentable technology regarding optimal administration of 4-AP. C8-9; C17; C101-103. To secure the best chance of gaining FDA approval for any neurological treatment using 4-AP, Acorda had to enter into the 2003 Agreements, C7, C53-54, including acceding to Alkermes’s demands to be the near sole-source supplier (C48, C61-62), to tie the Agreements for Alkermes to receive 18% on NSP, and to force Acorda to pay a “compensating payment” when Alkermes was not manufacturing the product. C49-50; C145; C222.

The Parties’ intent in forming the 2003 Agreements was for Acorda to obtain

a license for the '938 Patent to operate freely in the research and commercialization of a 4-AP formulation and to obtain supply of the formulation. C53. The Supply Agreement is incorporated into the License Agreement as Schedule 8 and was never separated from the license. Under Clause 11.1 of the Supply Agreement, the Supply Agreement expires immediately “upon expiry or termination of the License Agreement, howsoever arising.” C45. The two agreements operate in tandem and in the eyes of the law are one instrument.<sup>16</sup> When read together, the License and Supply Agreements required Acorda to pay a combined royalty of 18%. C24, C46; C202.

**B. Alkermes Used Monopoly Influences To Extract Over-Market Supply Pricing Unlawfully after Patent Expiration.**

The cross-default provisions in the License and Supply Agreements (C43-C44) reflect the Parties' intent that when the '938 Patent expired, both Agreements would expire, allowing Acorda the opportunity to negotiate a market “Supply Price.” Acorda never contemplated that the 8% supply royalties would extend into perpetuity or beyond patent expiry. C204. Acorda also reasonably expected that Alkermes would be amenable to discussing a market rate for supply at such time. *Id.* In contrast, however, Alkermes extended its monopoly influences beyond its patent term and extracted a grossly above-market “Supply Price” when the '938 Patent expired, rather than recognize termination of the License and Supply Agreements.

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<sup>16</sup> *Liberty USA Corp. v. Buyer's Choice Insurance Agency LLC*, 386 F.Supp.2d 421, 425 (S.D.N.Y. 2005).

Acorda did not expressly address the “Supply Price” in its communications with Alkermes after the ’938 Patent expired because Acorda believed that terminating the License Agreement was a predicate for terminating the Supply Agreement. C110, C121. Moreover, the termination clause in the Supply Agreement permits Alkermes to terminate any time for any reason on 12 months’ notice, while Acorda may recognize termination *only if* the License Agreement terminates. C52.

**C. Alkermes’s Supply Price Is Magnitudes Above Market Price.**

From Q3 2018 to Q1 2020, Acorda has paid, on average, \$155 per unit of Ampyra as a Supply Price to Alkermes. C203. That is magnitudes higher than the reasonable supply price of \$15 per unit of Ampyra in a competitive market. C204-207, 213. As a result, Acorda has paid \$8,946,573 more than the reasonable value for Alkermes’s manufacture of Ampyra since July 8, 2020. *Id.*; U70.

Alkermes’s own documents reveal that it earns an *811.11%* profit on supply of Ampyra to Acorda. C210. Mr. Lee testified also testified based on his 14 years of experience, that, unlike here, the cost of goods sold for small molecule drugs is often in the low single digit percent of revenue (manufacturing cost and royalties). C208-11, C218-221. Alkermes did not dispute this fact.

Mr. Malackowski also confirmed the unreasonableness of the “Supply Price” and that it is magnitudes higher than the reasonable price of \$15 for Ampyra in a competitive market. C204-207. Based on his extensive experience evaluating the

sale of branded pharmaceuticals in a generic market (C73), Mr. Malackowski considered evidence that alternative suppliers could manufacture Ampyra for a fraction of the cost that Alkermes charges Acorda. C207, C215. He also considered that *Alkermes* itself estimates generics COGS at \$14.87 per bottle, based on “ALKS cost + 40%”. C208, C210. Additionally, the supply price Alkermes charged for the Authorized Generic, *as manufactured by Alkermes*, was a fraction of the cost it charged Acorda *for the same exact drug*. C214. Dr. Addanki offered no alternative analysis of a reasonable supply price in a competitive market. C216-217.

#### IV. ACORDA IS ENTITLED TO THE RELIEF REQUESTED.

##### A. The Agreements Are Unenforceable As A Matter of Law.

As in *Brulotte*, the License and Supply Agreements “draw no line between the term of the patent and the post-expiration period.”<sup>17</sup> This is undisputed: Alkermes’s in-house lawyer testified that the 2003 Agreements have “a combined royalty on both Elan patents and Elan know-how which was *undifferentiated*,” that “continues to be paid for the length of the agreement.” C57. Under *Brulotte*:

[t]he contracts are, therefore, on their face a bald attempt to exact the same terms and conditions for the period after the patents have expired as they do for the monopoly period. [And this Panel], therefore, [is] unable to conjecture what the bargaining position of the parties might have been and what resultant arrangement might have emerged had the provision for post-expiration royalties been divorced from the patent and nowise subject to its leverage. *Id.*

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<sup>17</sup> *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964)

Under New York law, “the use of such an arrangement constitutes patent misuse even in the absence of evidence demonstrating that the patent holder used the leverage of the patent coercively to impose an extended term on the licensee.”<sup>18</sup> Here, the evidence is clear that Elan used its leverage to exact onerous terms from Acorda with the intent that they continue in perpetuity. *See, e.g.*, C4, C8-10, C133. “[W]here there is evidence of market power leverage arising from the patent which permitted the patentee to dictate contract terms extending beyond the life of the patent,” courts have held the agreements to be unenforceable and they “have refused to separate the potentially lawful from the unlawful.”<sup>19</sup>

The *Sanford Redmond* decision is controlling. There, the patentee of a critical patent refused to license its patent and instead offered to lease machines incorporating the patented process in perpetuity “on non-negotiable terms and conditions that would not likely have been obtainable without the patent excluding competition.”<sup>20</sup> Because the lease payments continued beyond the patent term, the court held that the use of the patent “to obtain an agreement for payment of compensation beyond the expiration of the patent renders the agreement unlawful

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<sup>18</sup> *Leesona Corp.*, 522 F.Supp. at 1342.

<sup>19</sup> *Sanford Redmond, Inc. v. Mid-America Dairymen, Inc.*, 1992 U.S. Dist Lexis 2376, \*15-16 (S.D.N.Y. 1992) (citing *Pitney Bowes, Inc.*, 701 F.2d at 1371; *Boggild v. Kenner Products*, 776 F.2d 1315, 1319 (6th Cir. 1985); *Meehan v. P.P.G. Industries, Inc.*, 802 F.2d 881, 885 (7th Cir. 1986)).

<sup>20</sup> *Sanford Redmond Inc.*, 1992 U.S. Dist Lexis 2376 at \*17.

*per se.*” *Id.* The court rejected the argument that other lease provisions were severable and enforceable, and held “*the entire contract...is unenforceable. This is the law in this district.*”<sup>21</sup> Where “illegality infects and destroys [an] agreement,” the illegal provisions cannot be severed.<sup>22</sup> Every New York case to have analyzed whether a *Brulotte* violation infects the entire agreement has answered the question in the affirmative, finding the entire contract unenforceable.<sup>23</sup>

The Supreme Court also addressed this issue in *Kimble*, where the underlying agreement transferred both patented and non-patented rights to Marvel.<sup>24</sup> There too, the agreement contained a severability clause, yet the Supreme Court affirmed the underlying judgment rendering the entire agreement unenforceable. The same result is required here.

## **B. Acorda Is Entitled To Declaratory Relief And Damages.**

Declaratory Relief – Claims 1, 2 & 3: This Panel has jurisdiction under the Declaratory Judgment Act to determine the rights and legal relations of parties to a

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<sup>21</sup> *Id.* at \*17-18 (emphasis added) (citing *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*, 299 F. Supp. 278, 282-83 (S.D.N.Y. 1969), *rev’d on other grounds*, 420 F.2d 319 (2d Cir.); *Noto v. Satloff*, 38 Misc. 2d 915, 239 N.Y.S.2d 324 (1963); *Am. Store Equipment & Construction Corp. v. Jack Dempsey's Punch Bowl, Inc.*, 174 Misc. 436, 21 N.Y.S.2d 117 (N.Y. Sup. Ct. 1939).

<sup>22</sup> *McCall v Frampton*, 81 A.D.2d 607, 608-609 (N.Y. App. Div. 2d Dept. Apr. 13, 1981). *See also Carruthers v Flaum*, 365 F. Supp. 2d 448 (S.D.N.Y. 2005).

<sup>23</sup> *See Veltman v. Norton Simon, Inc.*, 425 F. Supp. 774, (S.D.N.Y. 1977); *Sanford Redmond, Inc. v. Mid-America Dairymen, Inc.*, C.A. No. 85 Civ. 4574, 1992 WL 57090 (S.D.N.Y. Mar. 4, 1992).

<sup>24</sup> *Kimble*, 727 F. 3d at 860.

contract, so long as the case-or-controversy requirement is satisfied.<sup>25</sup> For any actual controversy within its jurisdiction, a tribunal “may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”<sup>26</sup>

Here, an actual case or controversy exists as to whether the underlying Agreements violate *Brulotte* and if so, the effect of that violation on the enforceability of the Agreements and the licensing and supply royalties. Based on the unequivocal evidence and the law, Acorda respectfully requests that the Panel enter the following declaratory judgment relief in its Award:

1. A *Brulotte* violation exists with regard to the underlying Agreements, and there is no legally cognizable exception that applies in this case.
2. Pursuant to the controlling legal principles set forth in *Brulotte* and its progeny, the underlying Agreements are unlawful *per se* and are unenforceable;
3. As a result of the foregoing, Alkermes was not entitled to collect patent or supply royalties following the expiration of the '938 Patent (July 30, 2018).

Unjust Enrichment – Claim 4: Having demonstrated that a *Brulotte* violation exists, Acorda is entitled to recover the monies paid to Alkermes that it was not entitled to collect.<sup>27</sup> Since expiration of the '938 Patent, Acorda has paid Alkermes over \$80 million in royalties and above-market supply prices. In Order #23,

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<sup>25</sup> See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126, 137 (2007).

<sup>26</sup> 28 U.S.C. § 2201.

<sup>27</sup> *Norman v. Salomon Smith Barney, Inc.*, 350 F. Supp. 2d 382, 389-80 (S.D.N.Y. 2004) (allowing restitution under a contract “rendered ‘void’ and unenforceable”).

however, the Panel determined that “any potential remedy Acorda continues to have is one pursuant to a theory of unjust enrichment/restitution for payments made under protest beginning in July 2020.” (This is \$57 million less than Acorda paid to Alkermes after patent expiry.) Although Acorda maintains that the law provides recovery of all payments made pursuant to the unlawful and unenforceable Agreements, the amount Acorda has paid since July 2020 is \$23,905,401.

Prejudgment Interest: Pursuant to N.Y.C.P.L.R. § 5001 (McKinney), Acorda is also entitled to recover prejudgment interest at the statutory rate (9% per annum) from the date the improper payments were made until the date the Panel renders a final Award, and continuing thereafter until the Award is merged into a final Judgment.<sup>28</sup> A preliminary calculation of prejudgment interest that has accrued through the date of Closing Argument will be provided to the Panel at that time.

### **CONCLUSION**

For the reasons set forth herein and in the accompanying Findings of Fact—and based on Alkermes’s *Brulotte* violation and unjust enrichment—Acorda respectfully requests that the Panel enter an arbitration award granting the declaratory relief set forth above and awarding Acorda \$23,905,401 in damages along with prejudgment interest.

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<sup>28</sup> AAA, Commercial Arbitration Rules, Rule R-47(d); *see also*, Reisberg, *et. al.*, “An Arbitrator’s Authority to Award Interest on an Award Until Date of Payment: Problems and Limitations.” Int. A.L.R., Issue 1 (2013), pp. 25-30.

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Respectfully submitted,

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